

PTO-1449 REPRODUCED

ATTORNEY DOCKET NO.  
3506.1000-002APPLICATION NO.  
10/757,364SUPPLEMENTAL INFORMATION DISCLOSURE  
STATEMENT  
IN AN APPLICATIONFIRST NAMED INVENTOR  
Steven B. LandauFILING DATE  
January 13, 2004

September 29, 2006

EXAMINER  
Yong Soo ChongCONFIRMATION NO.  
3343GROUP  
1617

(Use several sheets if necessary)

## U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
yc	AD6	US 2005/0239792	10-27-2005	Cavalla <i>et al.</i>
	AE6	US 6,008,227	12-28-1999	Davies <i>et al.</i>

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
	AQ3	EP 0 150 469	06-15-1988	Mitsubishi		
	AL4	CA 2431074	6-27-2002	Merck Patent GMBH		
	AM4	DE 100 63 223	6-20-2002	Merck Patent GMBH		

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)


	AWS	Crowell, M. D., "The Role of Serotonin in the Pathophysiology of Irritable Bowel Syndrome," <i>Am. J. Man. Care</i> , 7: S252-S260 (2001).
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EXAMINER

*Yong Chong*

DATE CONSIDERED

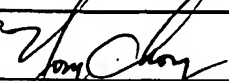
7/16/07

PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 3506.1000-002	APPLICATION NO. 10/757,364	
 <p>INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION</p> <p>May 24, 2006</p> <p>(Use several sheets if necessary)</p>		FIRST NAMED INVENTOR Steven B. Landau		FILING DATE January 13, 2004
		EXAMINER Yong Soo Chong	CONFIRMATION NO. 3343	GROUP 1617

U.S. PATENT DOCUMENTS				
EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
yc	AF5	6,475,078 B2	11-05-2002	Jerussi <i>et al.</i>
	AG5	2004/0254168 A1	12-16-2004	Landau
	AH5	2004/0254169 A1	12-16-2004	Landau
	AJ5	2004/0254170 A1	12-16-2004	Landau
	AJ5	2004/0259862 A1	12-23-2004	Landau
	AK5	2005/0032780 A1	02-10-2005	Landau
	AA6	2004/0254171 A1	12-16-2004	Landau <i>et al.</i>
	AB6	2004/0254172 A1	12-16-2004	Landau <i>et al.</i>
	AC6	2004/0147510 A1	07-29-2004	Landau

FOREIGN PATENT DOCUMENTS					
		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO
	AP3	WO 2004/062624 A3	07-29-2004	Dynogen Pharmaceuticals, Inc.	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AS5	Steadman, C.J., <i>et al.</i> , "Selective 5-Hydroxytryptamine Type 3 Receptor Antagonism With Ondansetron as Treatment for Diarrhea-Predominant Irritable Bowel Syndrome: A Pilot Study," <i>Mayo Clinic Proc.</i> , 67(8): 732-738 (1992).	
AT5	"Dynogen Pharmaceuticals, Inc. Enters Into Agreement With Mitsubishi Pharma For Irritable Bowel Syndrome Compound," Dynogen Pharmaceuticals, Inc. Press Release, pp. 1-2 [online], (December 22, 2003). Retrieved from the Internet <URL: <a href="http://www.dynogen.com">www.dynogen.com</a> >.	
AU5	Database IMSDRUGNEWS, R&D Focus Drug News, "DDP 225 Dynogen, Mitsubishi Pharma Licensing Agreement," [online], January 12, 2004. Retrieved from: STN Database, Accession No. 2004:188.	
AV5	Database CIN 2004-01-05, "Life Sciences in Brief," [online], January 5, 2004 (retrieved online January 31, 2006). Retrieved from: STN Database, Accession No. 33(3):1518T..	

EXAMINER 	DATE CONSIDERED 7/6/07
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EXAMINER <i>Y. Choy</i>	DATE CONSIDERED <i>7/16/07</i>
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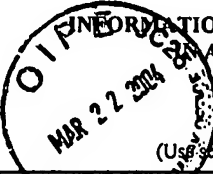
PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 3506.1000-002		APPLICATION NO. 10/757,364	
<b>SUPPLEMENTAL INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b>  <b>December 6, 2004</b> (Use several sheets if necessary)		FIRST NAMED INVENTOR Steven B. Landau		FILING DATE January 13, 2004	
		EXAMINER		CONFIRMATION NO. 3343	GROUP 1653

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
46	ALJ	WO 2004/058353 A3	07-15-2004	Amedis Pharmaceuticals, LTD.		

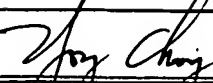
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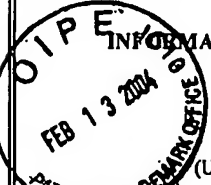


PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 3506.1000-002		APPLICATION NO. 10/757,364	
 INFORMATION DISCLOSURE CITATION IN AN APPLICATION March 19, 2004 (Use several sheets if necessary)		FIRST NAMED INVENTOR Steven B. Landau		FILING DATE January 13, 2004	
		EXAMINER Unknown		CONFIRMATION NO. Unknown	

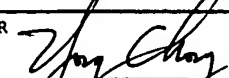
U.S. PATENT DOCUMENTS				
EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
Yc	AB5	2003/0158221 A1	08-21-2003	Zhang <i>et al.</i>

FOREIGN PATENT DOCUMENTS					
		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO
Yc	AQ2	WO 03/061657 A1 ✓	07-31-2003	Aryx Therapeutics	


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PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 3506.1000-002	APPLICATION NO. 10/757,364	
 <p>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</p> <p>February 11, 2004</p> <p>(Use several sheets if necessary)</p>		FIRST NAMED INVENTOR Steven B. Landau		FILING DATE January 13, 2004
		EXAMINER Unknown	CONFIRMATION NO. Unknown	GROUP Unknown


U.S. PATENT DOCUMENTS				
EXAM- INER INI- TIAL	REF. NO.	DOCUMENT NUMBER Number-Kind Code (if known)	ISSUE DATE / PUBLICATION DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT
YL	AA	4,695,568	09-22-1987	Ninomiya <i>et al.</i>
	AB	4,939,136	07-03-1990	Haeck <i>et al.</i>
	AC	5,225,407	07-06-1993	Oakley <i>et al.</i>
	AD	5,352,685	10-04-1994	Maruyama <i>et al.</i>
	AE	5,434,174	07-18-1995	Gidda <i>et al.</i>
	AF	5,438,068	08-01-1995	Eeckhout <i>et al.</i>
	AG	5,470,868	11-28-1995	Young
	AH	5,576,317	11-19-1996	Gonsalves
	AK	5,663,343	09-02-1997	van der Meij <i>et al.</i>
	AJ	5,945,415	08-31-1999	Kato <i>et al.</i>
	AK	5,962,494	10-05-1999	Young
	AA2	5,977,175	11-02-1999	Lin
	AB2	5,985,866	11-16-1999	Müller <i>et al.</i>
	AG2	5,990,159	11-23-1999	Meulemans <i>et al.</i>
	AD2	6,054,461	04-25-2000	Fairbanks <i>et al.</i>
	AE2	6,117,879	09-12-2000	Fairbanks <i>et al.</i>
	AF2	6,156,771	12-05-2000	Rubin <i>et al.</i>
	AG2	6,235,745 B1	05-22-2001	Megens
	AH2	6,284,770 B1	09-04-2001	Mangel <i>et al.</i>
	AI2	6,300,336 B1	10-09-2001	Eeckhout <i>et al.</i>
	AJ2	6,355,647 B1	09-12-2000	Steiner <i>et al.</i>
	AK2	6,384,042 B2	05-07-2002	Färber <i>et al.</i>
	AA3	6,429,209 B2	08-06-2002	Mangel <i>et al.</i>
	AB3	6,440,453 B1	08-27-2002	Fischer <i>et al.</i>
	AC3	6,441,038 B1	08-27-2002	Loder <i>et al.</i>
	AD3	6,458,795 B1	10-01-2002	Bergeron, Jr.

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PTO-1449 REPRODUCED  February 11, 2004 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3506.1000-002	APPLICATION NO. 10/757,364	
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46	AE3	6,465,458 B1	10-15-2002	Wong <i>et al.</i>
	AF3	6,566,369 B2	05-20-2003	Cautreels <i>et al.</i>
	AG3	6,588,708 B1	05-06-2003	Lin
	AH3	2001/0020025 A1	09-06-2001	Megens
	AJ3	2001/0044450 A1	11-22-2001	Mangel <i>et al.</i>
	AJ3	2001/0056110 A1	12-27-2001	Faerber <i>et al.</i>
	AK3	2002/0002197 A1	01-03-2002	Mueller <i>et al.</i>
	AA4	2002/0040033 A1	04-04-2002	Cautreels <i>et al.</i>
	AB4	2002/0086880 A1	07-04-2002	Rubin <i>et al.</i>
	AC4	2002/0086881 A1	07-04-2002	Rubin <i>et al.</i>
	AD4	2002/0107244 A1	08-08-2002	Howard, Jr.
	AE4	2003/0125349 A1	07-03-2003	Cautreels <i>et al.</i>
	AF4	2003/0203055 A1	10-30-2003	Rao <i>et al.</i>
	AG4	6,593,336 B2	07-15-2003	Mangel <i>et al.</i>
	AH4	2003/0036549 A1	02-20-2003	Mangel <i>et al.</i>
	AI4	6,211,171 B1	04-03-2001	Sawynok <i>et al.</i>
	AJ4	5,530,008	06-25-1996	Azcona <i>et al.</i>
	AK4	5,977,127	11-02-1999	Bonnacker <i>et al.</i>
	AA5	4,845,092	07-04-1989	Sanger <i>et al.</i>


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		EXAMINER Unknown	CONFIRMATION NO. Unknown	GROUP Unknown

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46	AR	Depoortere, I., <i>et al.</i> , "Dose-Dependent Effects of Recombinant Human Interleukin-11 on Contractile Properties in Rabbit 2,4,6-Trinitrobenzene Sulfonic Acid Colitis <sup>1</sup> ," <i>J. Pharmacol. Exp. Ther.</i> , 294(3): 983-990 (2000).
	AS	Million, M., <i>et al.</i> , "Susceptibility of Lewis and Fischer Rats to Stress-induced Worsening of TNB-colitis: Protective Role of Brain CRF," <i>Amer. Phys. Soc.</i> , 276 (4 Pt 1): G1027-G1036 (1999).
	AT	Owens, M. J., <i>et al.</i> , "Neurotransmitter Receptor and Transporter Binding Profile of Antidepressants and their Metabolites <sup>1</sup> ," <i>J. Pharmacol. Exp. Ther.</i> , 283(3): 1305-1322 (1997).
	AU	Kozlowski, C.M., <i>et al.</i> , "The 5-HT <sub>3</sub> Receptor Antagonist Alosetron Inhibits the Colorectal Distention Induced Depressor Response and Spinal <i>c-fos</i> Expression in the Anaesthetised Rat," <i>Gut</i> , 46: 474-480 (2000).
	AV	Ito, C., <i>et al.</i> , "Effect of GK-128 [2-[(2-Methylimidazol-1-yl)methyl]-benzo[f]thiochromen-1-one Monohydrochloride Hemihydrate], a Selective 5-Hydroxytryptamine <sub>3</sub> Receptor Antagonist, on Colonic Function in Rats," <i>J. Pharmacol. Exp. Ther.</i> , 280(1): 67-72 (1997).
	AW	Eguchi, J., <i>et al.</i> , "Pharmacological Profile of the Novel Antidepressant 4-(2-Fluorophenyl)-6-methyl-2-(1-piperazinyl)thieno-[2,3-d]pyrimidine Monohydrate Hydrochloride," <i>Arzneimittelforschung</i> , 47(12): 1337-1347 (1997).
	AX	Venkova, K., <i>et al.</i> , "Peripheral Activity of a New NK <sub>1</sub> Receptor Antagonist TAK-637 in the Gastrointestinal Tract," <i>J. Pharmacol. Exp. Ther.</i> , 300(3): 1046-1052 (2002).
	AY	Yuan, S.Y., <i>et al.</i> , "Investigation of the Role of 5-HT <sub>3</sub> and 5-HT <sub>4</sub> Receptors in Ascending and Descending Reflexes to the Circular Muscle of Guinea-pig Small Intestine," <i>Br. J. Pharmacol.</i> , 112(4): 1095-1100 (1994).
	AZ	Jin, J.G., <i>et al.</i> , "Propulsion in Guinea Pig Colon Induced by 5-Hydroxytryptamine (HT) Via 5-HT <sub>4</sub> and 5-HT <sub>3</sub> Receptors <sup>1</sup> ," <i>J. Pharmacol. Exp. Ther.</i> , 288(1): 93-97 (1999).
	AR2	Greenbaum, D.S., <i>et al.</i> , "Effects of Desipramine on Irritable Bowel Syndrome Compared with Atropine and Placebo," <i>Digestive Diseases and Sciences</i> , 32(3): 257-266 (1987).
	AS2	Center for Drug Evaluation and Research Application Number: 020623; Pharmacology Reviews; July 5, 1996.

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		EXAMINER Unknown	CONFIRMATION NO. Unknown	GROUP Unknown

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
4c	AT2	Eguchi, J., <i>et al.</i> , "The Anxiolytic-Like Effect of MCI-225, A Selective NA Reuptake Inhibitor with 5-HT <sub>2</sub> Receptor Antagonism," <i>Pharm. Biochem. and Behavior</i> , 68:677-683 (2001).
	AU2	Schmulson, M.J., "Brain-Gut Interaction in Irritable Bowel Syndrome: New Findings of a Multicomponent Disease Model," <i>IMAJ</i> , 3:104-110 (2001).
	AV2	Camilleri, M., "Serotonergic Modulation of Visceral Sensation: Lower Gut," <i>Gut</i> 51(1):81-86 (2002).
	AW2	Camilleri, M., "Serotonergic Drugs: Emerging Therapies for Irritable Bowel Syndrome," In <i>Irritable Bowel Syndrome a Clinician's Guide</i> , M. Camilleri and R. C. Spiller, eds., Chapt. 19; pp 1-10 (2002).
	AX2	Wood, J.D., <i>et al.</i> "Fundamentals of Neurogastroenterology," <i>Gut</i> 45(2):II6-II16 (1999).
	AY2	Burns, M.J., "The Pharmacology and Toxicology of Reboxetine," <i>Int. J. Med. Toxicol.</i> 3(4):26 1-8 (2000).
	AZ2	Thompson, W.G., <i>et al.</i> , "Functional Bowel Disorders and Functional Abdominal Pain," <i>Gut</i> 45:II43-II47 (1999).
	AR3	Sheikh, M. Y. and Wright, R.A., "Irritable Bowel Syndrome: Current Concepts and Future Prospects," <i>Hospital Physician</i> , pp. 31-38 (March 1999).
	AS3	Schmulson, M.J., "Brain-Gut Interaction in Irritable Bowel Syndrome: New Findings of a Multicomponent Disease Model," <i>IMAJ</i> 3:104-110 (2001).
	AT3	Gebhart, G.F., "Pathobiology of Visceral Pain: Molecular Mechanisms and Therapeutic Implications IV. Visceral Afferent Contributions to the Pathobiology of Visceral Pain," <i>Am. J. Physiol. Gastrointest. Liver Physiol.</i> 278:G834-G838 (2000).
	AU3	Mertz, H.R., "Irritable Bowel Syndrome," <i>N. Engl. J. Med.</i> 349:2136-2146 (2003).
	AV3	Bymaster, F.P., <i>et al.</i> "Comparative Affinity of Duloxetine and Venlafaxine for Serotonin and Norepinephrine Transporters <i>In Vitro</i> and <i>In Vivo</i> , Human Serotonin Receptor Subtypes, and Other Neuronal Receptors," <i>Neuropsychopharmacology</i> , 25(6):871-880 (2001).
	AW3	Béïque, J.C., <i>et al.</i> , Affinities of Venlafaxine and Various Reuptake Inhibitors for the Serotonin and Norepinephrine Transporters," <i>Eur. J. Pharmacol.</i> , 349(1):129-132 (1998).

EXAMINER <i>[Signature]</i>	DATE CONSIDERED 7/16/07
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		EXAMINER Unknown	CONFIRMATION NO. Unknown	GROUP Unknown

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

4C	AX3	Wong, E.H.F., <i>et al.</i> , "Reboxetine: A Pharmacologically Potent, Selective, and Specific Norepinephrine Reuptake Inhibitor," <i>Biol. Psychiatry</i> , 47(9): 818-829 (2000).
	AY3	Sach, J.A., <i>et al.</i> , "Irritable Bowel Syndrome," <i>Curr. Treat. Options. Gastroenterol.</i> , 5(4): 267-278 (2002).
	AZ3	Angel, I., <i>et al.</i> "Litoxetine: A Selective 5-HT Uptake Inhibitor with Concomitant 5-HT <sub>3</sub> Receptor Antagonist and Antiemetic Properties," <i>Eur. J. Pharmacol.</i> , 232(2-3):139-145 (1993).
	AR4	Fairweather, D.B., <i>et al.</i> , "The Psychomotor and Cognitive Effects of Litoxetine in Young and Middle Aged Volunteers," <i>Br. J. Clin. Pharmacol.</i> , 40(2):119-125 (1995).
	AS4	Morteau, O., <i>et al.</i> , "Influence of 5-HT <sub>3</sub> Receptor Antagonists in Visceromotor and Nociceptive Responses to Rectal Distension Before and During Experimental Colitis In Rats," <i>Fundam. Clin. Pharmacol.</i> , 8(6):553-562 (1994).
	AT4	Goldberg, P.A., <i>et al.</i> , "Modification of Visceral Sensitivity and Pain in Irritable Bowel Syndrome by 5-HT <sub>3</sub> Antagonism (Ondansetron)," <i>Digestion</i> , 57(6):478-483 (1996).
	AU4	LOTRONEX - Tablets, <i>Product Information</i> , GlaxoSmithKline, Research Triangle Park, NC, pp. 1-13 (2002).
	AV4	"Irritable Bowel Syndrome at a Glance - Nosology, Epidemiology, and Pathophysiology (Monograph I), December 2002 [Retrieved on 2002-12-12]. Retrieved from the Internet <URL:http://fdhn.org/html/education/gi/ibs_nosology.htm>
	AW4	U.S. Provisional Application No. 60/364,531, filed 03-15-2002, entitled "Methods of Treating Visceral Pain Syndromes," by Rao <i>et al.</i> , priority document for WO 03/077897 A1 (Reference AQ2) and U.S. 2003/0203055 A1 (Reference AF4).
	AX4	GB 0304648.9, filed 02-28-2003, entitled "New Therapeutic Use of 4-(2-Fluorophenyl)-6-Methyl-2-(1-Piperziny) Thieno[2,3-D] Pyrimidine," priority document for WO 2004/004734 A1 (Reference AL2).
	AY4	GB 0216027.3, filed July 10, 2002, entitled "New Therapeutic Use," priority document for WO 2004/004734 A1 (Reference AL2).
	AZ4	Drossman, D.A., <i>et al.</i> , "Irritable Bowel Syndrome: A Technical Review for Practice Guideline Development," <i>Gastroenterology</i> , 112: 2120-2137 (1997).

EXAMINER <i>[Signature]</i>	DATE CONSIDERED <i>7/10/07</i>
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